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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,230	05/17/2002	Naresh Kumar	RLL-159US	5863

7590

06/09/2003

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 06/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/009,230

Applicant(s)

KUMAR ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. This application is a 371 of PCT/IB00/00708. The 371 date is May 17, 2002.
2. The abstract attached to the application is inappropriate for printing since it contained many information. It is recommended that complete revision of the content of the abstract is required on a separate sheet, in one paragraph less than 250 words. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Coutant et al.

#### J. Chrom.

The claimed fexofenadine was isolated from the physiological system (see p.140, compound (b)) which in its native environment should be an acid addition salt of the chloride since the cyclic amine should be in its acid addition form and chloride is the most abundant anion in blood. In blood, the fexofenadine hydrochloride is in liquid state. All liquid are amorphous, therefore, anticipation is found.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meiwes et al. US 5,990,127 in view of Berge et al.

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Meiwes et al. '127 disclosed lyophilized product of compound 1 (see col. 7 line 55-60, col. 8 lines 19-21) which is the instant claimed parent compound. An acid addition salt of the known compound is considered prima facie obvious since acid addition salt is a pharmaceutical formulation well known in the art and hydrochloric acid is an FDA approved salt forming acid (see Berge p.2).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. US 4,254,129, 4,285,957, or WO 95/31437 (all cited on 1449) or Woosley Us 5,375,693 in view of Lieberman, Susukin, Corrigan Nuernberg (all cited on 1449) and Sato CA 110 supplemented with US 5,990,127.

Determination of the scope and content of the prior art (MPEP §2141.01)

The primary references disclosed the claimed compound

See Carr '129, col. 13, example 3,

Carr '957 col. 13, example 3

WO 95/31429 claims 10-11, 13-15, 17-19, p. 11 lines 22-29 solvents

Woosley et al. '693, col. 10, example 1B, and solvent.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the amorphous form or process of spray dry, freeze dry etc. for preparing amorphous form was not explicitly disclosed. However, Lieberman, Suzuki, Corrigan, Nuernberg or Sato provided perponderous of evidence that spray drying or freeze drying process are size reduction processes for pharmaceutical products and such size reduction would enhance drug dissolution thus bioavailability (see Lieberman).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art in possession of the above references would be motivated to prepare the amorphous form of the drug **because** process of preparing the named compound is conventionally explicitly taught using the claimed solvents. One skilled in the art would be motivated to carry out the prior art process employing spray drying or freeze drying since it was clearly suggested by the prior art that spray drying and freeze drying are size reduction routine procedure in formulation which enhances drug dissolution, also such process would inherently produce the amorphous form. Further, the claimed product, when prepared

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from a biological resource, has been prepared routinely employing the procedure lyophilization which is freeze drying, thus, supplied evidence that spray drying and freeze drying are routine procedure in drug formulation.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Applicants' attention is drawn to US2002/01776608 and WO02/066429 wherein the US2002/01776608 is a potential 102(e) reference with 102(f) or (g) issues and the WO02/066429 reference is a potential 102(f) or (g) reference based on the 371 date of the instant application being may 17, 2002.

Please note that the US2002/01776608 has a US provisional date of April 9, 2001 and disclosed amorphous product of the claims, see page 10 example 1-6 with claimed process employing any drying step (see claims 1-10).

Claim 1 is provisionally rejected under 35 U.S.C. 102(e) (f) or (g) as being anticipated by US2002/01776608 or alternatively claims 1-13 are provisionally rejected under 35 USC 103(a) based on 102(f) or (g) reference US 2002/01776608. Please note that the more specific naming the drying process being spray dry or freeze dry are generically embraced by the claims of US2002/01776608 while all amorphous products are the same irrespective of process of making.

This is a provisional rejection since the US2002/01776608 are not yet patented.

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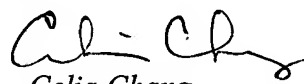
The WO02/066429 reference claimed the amorphous product and process of making for which the 371 date must be evaluated against the instant 371 date under potential 102(f) or (g) requirements.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang  
May 30, 2003



Celia Chang  
Primary Examiner  
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